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Wallenstein Wagner & Rockey, Ltd.
53rd Floor
311 S. Wacker Drive
Chicago, IL 60606-6622

EXAMINER

FICK, ANTHONY D

ART UNIT

PAPER NUMBER

1753

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/727,336 | Applicant(s) HAJIZADEH ET AL. | |
| | Examiner Anthony Fick | Art Unit 1753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/9/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: electrode segments 33 (page 11, line 24 of specification). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to because they fail to show the invention in claim 17 of "a body having a hinge constructed therein for permitting the pivoting and connecting of a portion of the body onto itself". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

Art Unit: 1753

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The disclosure is objected to because of the following informalities: the numerical reference on page 11, line 25 of the leads should be "30, 31, 32" not "31, 31, 32". Page 12, line 25 references a "transfer mediator may be applied to the same electrode 32" with the previously mentioned primary working electrode labeled as "30". Either the reference number should be changed from "32" to "30" or "same" should be changed to "secondary working".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

Art Unit: 1753

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The requirement of the claim for "a body having a hinge constructed therein for permitting the pivoting and connecting of a portion of the body onto itself" does not have any support in the specification to explain how one of ordinary skill in the art would reproduce this requirement. Also there is no indication in the drawings to clarify how this hinge structure fits into the sensor carrier.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1 and 3 through 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhullar et al. (U.S. 6,428,664).

Bhullar teaches an electrochemical device that can be used as a biosensor. As shown in figure 1, the device includes a carrier, reference number 10, which sits in an electronic meter capable of holding the carrier, moving the carrier, and measuring electrical properties. Bhullar teaches the carrier can be molded of insulative material (column 2, paragraph 9) and supports a plurality of channels or sensors (column 2, paragraph 8). These channels can be seen in figure 13 and constitute individual sensing elements. The channels contain a fluid-receiving portion, two spaced apart electrical conductors (column 4, paragraph 3), a reagent to change the electrical

properties between the electrodes upon reacting with the fluid sample (column 4, last paragraph), and a contact to provide communication with the meter (column 4, paragraph 4). All of these features are also shown in figure 5 and meet all the requirements of claim 1. As figure 1 shows, the carrier is a substantially circular disc, thus meeting claim 3. The meter moves the device by rotating the carrier (column 7, paragraph 1) as in claim 4. Also figure 1 shows the sensors are fixed within the carrier are not removable, and are radially spaced from one another spoking outwardly from the center of the disc. Thus claims 5 and 6 are also met. The inlets are capillaries and are along a periphery of the disc as in claim 7.

Bhullar further teaches electrodes formed by machining a conductive plate (column 10, paragraph 2). The conductive plate meets claim 8 and the machining into a specific pattern meets the requirements of claim 9 that the electrodes are stamped into a specific pattern.

8. Claims 1 through 6, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nozoe et al. (U.S. 5,556,533).

Nozoe teaches a chemical sensor and holder. The sensor has a substantially disc shaped carrier supporting a plurality of sensor elements (column 3, paragraph 4), a holder capable of housing the carrier, moving the carrier (column 3, paragraph 6), and measuring the electrical properties (column 4, paragraph 1). The sensors contain a plurality of spaced electrodes with contacts for the meter (column 3, paragraph 4) and substances on the electrodes to change the electrical properties between the electrodes upon reacting with the fluid sample (column 4, paragraph 7). Figures 19a, 19b and 20

Art Unit: 1753

further teach about the structure of the sensor displaying a fluid sample receiving portion and show an insulating material embedding a portion of the electrodes. Thus Nozoe teaches all the requirements of claim 1. Figure 18a shows the carrier with a plurality of sensors. From this figure, Nozoe shows the electrodes substantially molded into the insulative material of the carrier, the carrier is a substantially circular disc, the plurality of sensors are fixed within the carrier and not removable, and the sensors are radially spaced from each other spoking outwardly from the center of the disc. Thus claims 2, 3, 5, and 6 are met. Nozoe further teaches rotation as the method for moving the carrier (column 3, paragraph 6) thus meeting claim 4.

Nozoe teaches in figure 4, the end of the sensor extends outside the meter device to collect a sample. Since the reaction area is visible, there is visual indication means for detecting a sufficient amount of fluid sample. Nozoe further teaches applying a voltage across the electrodes to detect contact of the fluid sample with the electrodes (column 14, paragraph 5). Thus Nozoe meets claim 11. The teachings of Nozoe as applied to claim 1 can also be applied to claim 16. Nozoe further teaches the sensor can contain a second piece, a moisture proof cap that is attachable to the body of the sensor (column 9, paragraph 3, and figure 13). This meets claim 16.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nozoe as applied to claims 1 through 6, 11 and 16 above, and further in view of Diebold et al. (U.S. 5,437,999).

The teachings of Nozoe are as stated above for claims 1 through 6, 11 and 16.

The difference between Nozoe and claim 10 is the requirement at least one electrode is coated with a conductive material different than the composition of the electrode. Nozoe teaches the electrodes can be made using a conductive material printing process but does not teach different materials (Nozoe column 6, paragraph 1).

Diebold teaches an electrochemical sensor with a different method of producing the electrodes. Coating thin noble metal films onto an appropriate foil material and then laminating onto a support structure creates the electrodes (Diebold column 3, paragraph 1). Thus the electrodes are coated with a conductive material different than the composition of the electrode.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the electrodes of Diebold in the sensors of Nozoe because the electrode surfaces are nearly ideal for the purpose of making electrochemical measurements in biological solutions (Diebold column 3, paragraph 1). Since the sensors of Nozoe are utilized to measure biological solutions, these electrodes would be an obvious improvement to the device. Because both Diebold and Nozoe are concerned with electrochemical sensing of biological material, one would have a reasonable expectation of success from the combination. Thus the combination meets claim 10.

11. Claims 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhullar as applied to claims 1 and 3 through 9 above, and further in view of Segal et al. (U.S. 6,300,141).

The teachings of Bhullar are as stated above for claims 1 and 3 through 9.

The difference between Bhullar and claim 11 is the requirement for detecting a sufficient amount of the fluid sample has been received by the device by electrical indication or visual indication.

Segal teaches a card-based biosensor device including multiple sensors arranged on a circular disc (figure 24). In a preferred embodiment, Segal teaches a pair of sensing electrodes is placed within the reaction zone (column 9, paragraph 3). The presence of enough liquid sample bridges the electrodes, reduces the resistance across them, and sends a signal to indicate sufficient fill (column 9, paragraph 3).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the sensing electrodes of Segal within the reaction area of the sensors within the device of Bhullar because the sensors alert the operator when sufficient fluid has been placed into the reaction area. Thus the minimum amount of sample required for the test can be used to conserve the sample. Also the voltage required to carry out the test would not be applied until sufficient fluid is within the chamber, thereby reducing testing errors. These advantages are especially valuable to the device of Bhullar since the reaction zone is hidden from visual observation. Because both Segal and Bhullar are concerned with electrochemical sensing devices, one would have a reasonable expectation of success from the combination. Thus the

Art Unit: 1753

combination meets claim 11. Bhullar further teaches in figure 5, the reaction zone contains a cavity that is in fluid communication with the capillary inlet. Also the electrodes are exposed therein and in view of Segal are connected to activate a meter to indicate sufficient fill. Therefore, claims 14 and 15 are also met.

12. Claims 11 through 13 are rejected under 35 U.S.C. 103(a) as being obvious over Bhullar as applied to claims 1 and 3 through 9 above, and further in view of Rappin et al. (U.S. 6,572,745).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The teachings of Bhullar are as stated above for claims 1 and 3 through 9.

The difference between Bhullar and claim 11 is the requirement for detecting a sufficient amount of the fluid sample has been received by the device by electrical indication or visual indication.

Rappin teaches an electrochemical sensor containing a capillary inlet and a vent for relieving pressure (column 2, paragraph 4). Rappin further teaches the vent also could be used for a visual detection of fluid fill (column 3, paragraph 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the vent of Rappin in the reaction zone of Bhullar because the vent relieves pressure and aids in the capillary flow of the sample into the chamber (column 5, paragraph 1). The vent also provides a visual indicator to determine if sufficient fluid has been introduced into the sensor. Thus the minimum amount of sample required for the test can be used to conserve the sample. Also the voltage required to carry out the test would not be applied until sufficient fluid is within the chamber, thereby reducing testing errors. These advantages are especially valuable to the device of Bhullar since the original reaction zone is hidden from visual observation. Because both Rappin and Bhullar are concerned with electrochemical sensing, one would have a reasonable expectation of success from the combination. Thus the combination meets claims 11 and 12. Bhullar also teaches the reaction zone is in communication with a capillary inlet in figure 5, thus meeting claim 13.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nozoe as applied to claims 1 through 6, 11 and 16 above, and further in view of Davies et al. (U.S.P.G.Pub 2002/0092612).

Art Unit: 1753

The teachings of Nozoe are as stated above for claims 1 through 6, 11 and 16.

The difference between Nozoe and claim 17 is the requirement of a hinge constructed in the body of the sensor to permit pivoting and connecting of a portion of the body onto itself. Nozoe only teaches a waterproof cap placed on the end of the sensors to protect the reaction area.

Davies teaches a glucose sensor. The sensor is manufactured by depositing electrodes onto a substrate and then folded along a line to permit pivoting and connecting of a portion of the substrate onto itself (paragraph 0030, and figure 5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the folded sensors of Davies within the device of Nozoe because the folded geometry produces a thin layer of solution separating the electrodes and a low voltage drop due to solution (Davies paragraph 0030). Also the folding protects the reactive zone from contamination similar to the cap already taught by Nozoe without the additional process step of removing the cap before adding sample. Because both Davies and Nozoe are concerned with electrochemical sensors, one would have a reasonable expectation of success from the combination. Thus the combination meets claim 17.

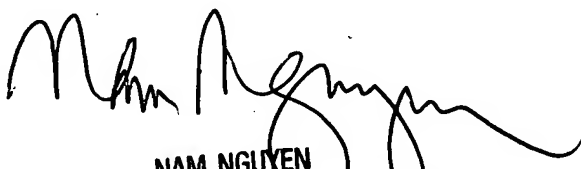
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony Fick whose telephone number is (571) 272-6393. The examiner can normally be reached on Monday thru Friday 8 AM to 5 PM.

Art Unit: 1753

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anthony Fick *ADF*
AU 1753
October 27, 2005


NAM NGUYEN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700